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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,268	09/09/2004	Seppo Yla-Herttuala	GJE-7452	4903

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
NOBLE, MARCIA STEPHENS	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
02/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,268	YLA-HERTTUALA ET AL.	
	Examiner	Art Unit	
	MARCIA S. NOBLE	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.1141.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/3/2007 has been entered.

2. The rejection of claims 1-9 made in the office action mailed August 9, 2007, under 35 U.S.C. 112, first paragraph because the specification did not fully enable the claims, is withdrawn. However, a new scope of enablement rejection has been made. See below.

Status of Claims

3. Claims 1, 5, 6, 8, and 9 are pending. Claims 2-4 and 7 are canceled and claims 1 and 6 are amended by the amendment filed 11/3/2007. Claims 1, 5, 6, 8 and 9 are under consideration.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

4. Claims 1, 5, 6, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a baculovirus comprising a vp39 fusion protein, wherein said fusion protein comprises a vp39 protein with an heterologous polypeptide fused to the C- or N- terminus of said vp39 protein and wherein said fusion protein is expressed on the surface of the baculovirus capsid, does not reasonably provide enablement for a baculovirus comprising vp39 fusion protein comprising any structural configuration and that also has a modification at the C- or N-terminus of the vp39 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of

working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

The claims broadly encompass a baculovirus that expresses a vp39 fusion protein comprising any structural configuration of two or more polypeptides and also comprising any modification to the C- or N- terminus of the vp39 protein, wherein the modification to the C- or N-terminus of the vp39 protein is independent of the composition of the fusion protein, such as an amino acid substitution, deletion or addition. Therefore, a fusion protein comprising a heterologous peptide inserted into the start, middle, or end of the vp39 amino acid sequence would encompass this first limitation of "a vp39 fusion protein". However the breadth of the claims is not enabled by the specification and the art for the following reasons.

The specification teaches the production of a baculovirus that expresses a vp39 fusion protein on its surface for purposes of viral surface display or gene therapy vector development (p. 1-2). The specification teaches a baculovirus that expresses on its surface a vp39 fusion protein comprising a vp39 protein and the heterologous polypeptide, GFP, fused to the C- or N-terminus of the vp39 protein (p. 15 -16).

The art at the time of filing teaches that not all such modifications would result in a vp39 that would still be functional in a baculovirus. Grabherr and Ernst (Combin Chem & High Throughput Screen 4:185-192, 2001) state, "One major constraint for all viral surface display strategies is the alteration of the viral coat protein to which the foreign proteins or peptides somehow have to be connected. Peptide insertions automatically change the structure of the coat protein, whereby the function, necessary

for infectivity may be impaired." (See page 185, col 2). As previously discussed in the Office Action, mailed 8/9/2006 on pages 5-7, "Oke-Blom et al (Briefing in Functional Genomics and Proteomis 2(3):244-253, 2003) suggest that the three dimensional structure of baculovirus *AcMNPV* has not been determined and therefore the structural interactions and functional elements of capsid proteins have not been fully described, developed, and understood (p. 249, col 1 par 1)." Since the structural/functional relationship of the capsid proteins in baculoviruses had not been well described in the art at the time of filing, an artisan would need to look to other examples in the art or specification to determine the structural functional/structural limitations necessary to retain functional capsid fusion proteins comprising exogenous polypeptides. Thomsen et al (J Virol 69(6):3690-3703, 1995) teaches that the C-terminal 25 amino acids of the UL26 and UL26.5 capsid protein must remain unaltered to assure proper assembly of the capsid in HSV-1 (see abtract). West et al teaches (J Virol 80(9):4458-4468, 2006) that the E2 domain (E2 amino acids 408 to 415) is critical for nucleocapsid formation an Sindbis virus assembly and that mutation in these residues result in failure to assemble virons (see abstract). Therefore the art suggests that there are limits to the types of modifications that can be made to capsid proteins of baculoviruses and still retain their structure/functional relationship and ultimately a functional baculovirus.

Since the art suggests that the structural/functional relationship of baculovirus capsid protein were not well established in the art at the time of filing and the art also suggests that there are limitations to the types of modifications that can be made to baculovirus capsid proteins and still maintain a functional baculovirus, an artisan would

look to the specification for guidance to determine which types of modification could be made to vp39 that would result in a functional vp39 protein in the modified baculovirus. The instant specification only teaches modifying vp39 by fusing an heterologous polypeptide to the N- and C- terminus of vp39 protein. Therefore, an artisan would only have guidance from the specification to produce a vp39 fusion protein that produces a functional baculovirus by fusing an exogenous polypeptide to the N- or C- terminus of vp39.

Therefore, given the nature of the art describing the structural/functional relationship of baculovirus capsid proteins at the time of filing, the modification of the vp39 to make a baculovirus comprising any other vp39 fusion protein other than a vp39 fusion protein comprising an heterologous polypeptide fused to the N or C terminus of the vp39 protein would be unpredictable. Therefore, the instant invention is not enable for the full breadth of a baculovirus comprising a vp39 fusion protein as claimed and is only enabled for a baculovirus comprising a vp39 fusion protein comprising an exogenous polypeptide fused to the N- or C- terminus of the vp39 protein.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 lacks antecedent basis for "said baculovirus." The claim should be amended to "said vector." Further, claims 8 and 9 should refer back to the "The Baculovirus vector" or "The vector", not "The Baculovirus" since "a vector" is subject matter of claim 6. Claims 8 and 9 are therefore improperly dependent on claim 6.

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch, Ph.D./
Primary Examiner, Art Unit 1632

Marcia S. Noble
AU 1632